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10/590,060	11/27/2006	Jane Evison	2955-231	4182

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,060	EVISON, JANE	
	Examiner	Art Unit	
	CRAIG RICCI	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44 and 46-54* is/are pending in the application.

4a) Of the above claim(s) *12,13,39-44 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 14-38, 49-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The amendments filed 7/01/2009 were entered.

Response to Arguments

2. Applicants' arguments, filed 7/01/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 1-11, 14-29 and 38 remain rejected and new claims 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Singh et al* (cited in a previous Action), *Singh and Roberts* (cited in a previous Action), *Hong et al* (cited in a previous Action), *Obata et al* (cited in a previous Action), and *Loffler et al* (cited in a previous Action).**

6. Instant claims 1-6 and 25 are drawn to a cosmetically acceptable skincare composition in the form of a hydroalcoholic gel dispersion, the composition comprising salicylic acid or a salt thereof (more specifically, salicylic acid – claim 25) and a gelling agent, more specifically wherein the gelling agent is ammonium acryloyldimethyltaurate / vinyl pyrrolidone (hereinafter Aristoflex AVC), and further provided that if the composition contains xantham gum then it does not contain iron trichloride.

7. As discussed in the previous Action mailed on 3/04/2009, and reiterated herein, cosmetically acceptable skincare compositions comprising salicylic acid in the forms of gels, lotions, creams and solutions are well known in the art to be safe and effective especially for the treatment of acne. As specifically disclosed by *Singh et al*, "[s]alicylic acid has been approved by the U.S. Food and Drug Administration for the treatment of acne in concentrations of 0.5% to 2% by weight. Such compositions may be in the form of a gel, lotion, cream or solution" (Column 1, Lines 16-19). However, *Singh et al* also teach that "salicylic acid is sparingly soluble in water" (Column 1, Line 21). Furthemore, *Singh and Roberts* teach that nonsteroidal anti-inflammatory drugs (NSAIDs), such as **salicylic acid**, show low skin permeability when topically applied (Pages 148-150, Figures 3-5). Notably, *Singh and Roberts* also disclose that ***other*** NSAIDs (in addition to salicylic acid), such as diclofenac and piroxicam, similarly show low skin permeability when topically applied (Pages 148-150, Figures 3-5).

8. In the case of piroxicam, *Hong et al* teach "a hydroalcoholic gel composition which can not only decrease the external loss of piroxicam but can increase the permeation of piroxicam through skin remarkably compared with [a] conventional hydrogel preparation" (Abstract). More specifically, the hydroalcoholic gel composition taught by *Hong et al* "comprises (a) 0.1~2% by weight of piroxicam; (b) 40~60% by weight of lower alkanol having from one to four carbon atoms; (c) 0.1~5% by weight of hydroxypropylcellulose or hydrophobic derivatives of hydroxypropylmethylcellulose, optionally comprising hydroxypropylmethlycellulose or carbomer… and (f) water" (abstract).

9. Furthermore, in the case of diclofenac, *Obata et al* demonstrate that ethanol enhances skin permeation of the NSAID by attacking the dense barrier structure of the skin (Abstract).

10. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to formulate a skincare composition comprising the NSAID **salicylic acid** in the form of a hydroalcoholic gel dispersion. The skilled artisan would have been motivated to do in view of *Singh and Roberts* - which teach that topical formulations of NSAIDs (such as salicylic acid and piroxicam) show low skin permeability - and in view of *Hong et al* which specifically teach that hydroalcoholic formulations comprising piroxicam decrease the external loss of the NSAID and increase permeation of the NSAID through the skin. Thus, the skilled artisan would have been motivated to provide salicylic acid in a hydroalcoholic gel dispersion in order to overcome the compound's low permeability. Although *Hong et al* is drawn to piroxicam, and not specifically to salicylic acid, the skilled artisan would have reasonably predicted that formulating salicylic acid in a hydroalcoholic gel dispersion would similarly enhance the compound's skin permeation since both of the compounds are NSAIDs

having similar mechanisms of action. Thus, the person of ordinary skill in the art would have predicted that a formulation which enhances the permeability of one NSAID compound (piroxicam, as taught by *Hong et al*) would also enhance the permeability of another NSAID (salicylic acid). More specifically, in view of *Obata et al*, which demonstrate that ethanol enhances skin permeation of the NSAID diclofenac by attacking the dense barrier structure of the skin (Abstract), the skilled artisan would have reasonably predicted that the hydroalcoholic gel dispersion taught by *Hong et al* (comprising ethanol (Pages 11-14, Examples 1-6 and Pages 17-8, Examples 8-18)) enhances piroxicam permeability by disrupting the skin barrier, a condition which would similarly enhance the permeation of salicylic acid. Accordingly, for all of the foregoing reasons, it would have been *prima facie* obvious to formulate the hydroalcoholic gel dispersion taught by *Hong et al* wherein the hydroalcoholic gel comprises salicylic acid (as recited by the instant claims) in place of piroxicam (as taught by *Hong et al*).

11. However, the hydroalcoholic gel dispersion taught by *Hong et al* comprises gelling agents such as "hydroxypropylcellulose or hydrophobic derivatives of hydroxypropylmethylcellulose optionally comprising hydroxypropylmethlycellulose or carbomer" (Page 5, Lines 2-4) whereas instant claims 1-6 are drawn to a hydroalcoholic gel dispersion comprising Aristoflex AVC as the gelling agent. *Loffler et al* teach Aristoflex as a gelling agent useful in hydroalcoholic gel disperstions. Specifcally, *Loffler et al* teach that "Aristoflex AVC is easy to use, as the polymer is pre-neutralized. Gelling takes place immediately when the polymer comes in contact with water" (Paragraph 4) and that "Aristoflex AVC is particularly suitable for modern cosmetics" (Paragraph 6). Moreover, *Loffler et al* disclose that "compatibility with polar organic solvents is of interest for the formulation of

hydro-alcoholic gels. Aristoflex AVC has good compatibility with polar organic solvents such as ethanol or acetone. Commercial application could be the formulation of hydro-alcoholic hair gels, antiseptic hand sanitizers or nail polish removers containing acetone" (Paragraph 9). *Loffler et al* further point out that "Aristoflex AVC can be used in a broad pH range" (Paragraph 8) and is "much more stable" to UV light and shear stress **than a typical carbomer** (Paragraphs 10-11).

12. *Loffler et al* conclude that "Aristoflex AVC… is pre-neutralized, it is easy to incorporate in any stage of the gel or emulsion formation. It has excellent stability against high shear forces and UV light. It tolerates low pH-values, high amounts of polar organic solvents and it allows formulation of emulsifier-free gels" (Final Paragraph). Thus, for all of these reasons, it would have been obvious to a person of ordinary skill in the art to formulate the hydroalcoholic gel dispersion taught by *Hong et al* using Aristoflex AVC as the gelling agent. The skilled artisan would have been motivated to do so for the reasons taught by *Loffler et al*. That is, the skilled artisan would have reasonably predicted that using Aristoflex AVC in place of the gelling agent taught by *Hong et al* would provide good stability against high shear forces and UV light, tolerate low pH values, and, significantly, high amounts of polar organic solvents such as ethanol in the formulation of hydroalcoholic gels.

13. For all of the foregoing reasons, claims 1-6 and 25 are rejected as *prima facie* obvious.

14. Applicants, however, traverse on the grounds that "the incremental leaps taken to bridge the gaps between the subject matter of each of the references is a propagation of hindsight that was improperly used to collect the five cited references" (Applicant Argument, Page 12). In response to Applicant's argument that the conclusion of obviousness is based upon improper

hindsight reasoning, it must be recognized that ***any*** judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392 (CCPA 1971). In the instant case, only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and no knowledge gleaned only from the Applicant's disclosure, has been been taken into account. Specifically, that knowledge is as discussed above and summarized as follows:

(1) Cosmetically acceptable skincare compositions comprising salicylic acid in the forms of gels, lotions, creams and solutions are well known in the art.

(2) However, as taught by *Singh et al* "**salicylic acid** is sparingly soluble in water" and, as taught by *Singh and Roberts* **salicylic acid** and other NSAIDs (such as piroxicam and diclofenac) show low skin permeability when topically applied.

(3) To enhance the solubility and skin permeability of piroxicam, *Hong et al* teach "a hydroalcoholic gel composition which can not only decrease the external loss of piroxicam but can increase the permeation of piroxicam through skin remarkably" comprising **ethanol**, a gelling agent, and water.

(4) Similarly, *Obata et al* demonstrate that **ethanol** enhances skin permeation of diclofenac by attacking the dense barrier structure of the skin.

(5) Accordingly, it would have been *prima facie* obvious to formulate the hydroalcoholic gel composition taught by *Hong et al* using salicylic acid in place of piroxicam to enhance the solubility and skin permeability of salicylic acid with a reasonable expectation of success. For example, based on *Obata et al*, the skilled artisan would have reasonably predicted that the hydroalcoholic gel composition would enhance the skin permeability of salicylic acid by the action of ethanol attacking the dense barrier structure of the skin.

(6) Furthermore, it would have been *prima facie* obvious to formulate the hydroalcoholic gel composition taught by *Hong et al* using Aristoflex AVC as the gelling agent in view of *Loffler et al*, who disclose numerous advantages of Aristoflex AVC over conventional gelling agents such as those disclosed by *Hong et al*, as discussed above.

15. Applicants, however, argue that "the combination of these references would not have motivated... the presently claimed invention" (Applicant Argument, Page 13). Specifically, Applicants argue that *Singh* discloses that alcohol can irritate the skin, teaching away from using alcohol in skin care compositions (Applicant Argument, Page 13; see also Applicant Argument, Page 15). Applicants' argument is not found persuasive. While it may be the case that alcohol can irritate the skin, the hydroalcoholic gel composition taught by *Hong et al* is specifically disclosed as showing "decreased skin irritation of alcohol" (Page 7, Line 26 to Page 8, Line 1). Accordingly, the skilled artisan would not have been dissuaded from formulating the hydroalcoholic gel composition comprising a large amount of ethanol taught by *Hong et al* using salicylic acid in place of piroxicam.

16. Additionally, Applicants argue that *Singh and Roberts* demonstrate poor predictability of the permeability of various compounds (Applicant Argument, Page 13). However, as previously discussed, the skilled artisan would have reasonably predicted that formulating salicylic acid in a hydroalcoholic gel dispersion would enhance the compound's skin permeation since, like peroxicam, salicylic acid is an NSAID having a similar mechanism of action. Thus, the person of ordinary skill in the art would have predicted that a formulation which enhances the permeability of one NSAID compound (piroxicam, as taught by *Hong et al*) would also enhance the permeability of another NSAID (salicylic acid). More specifically, in view of *Obata et al*, which demonstrate that ethanol enhances skin permeation of the NSAID diclofenac by attacking the dense barrier structure of the skin, the skilled artisan would have reasonably predicted that the hydroalcoholic gel dispersion taught by *Hong et al* (comprising ethanol) enhances piroxicam permeability by disrupting the skin barrier, a condition which would similarly enhance the permeation of salicylic acid. Under these circumstances, despite some unpredictability in the art, the skilled artisan would have still formulated the hydroalcoholic gel composition taught by *Hong et al* using salicylic acid in place of piroxicam to enhance the solubility and skin permeability of salicylic acid with a reasonable expectation of success. Applicants are reminded that obviousness does not require absolute predictability, only a reasonable expectation of success of obtaining similar properties. *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988).

17. Applicants also argue that *Hong et al* do not mention salicylic acid and, furthermore, there is no motivation after reading *Hong et al* to replace the disclosed gelling agent with the claimed gelling agent (Applicant Argument, Page 14). Applicants' argument is not considered persuasive. While it is acknowledged that *Hong et al* do not teach salicylic acid or the claimed

gelling agent, Applicants are reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986). As discussed above, in view of the combination of references, it would have been obvious to use salicylic acid and the claimed gelling agent in the composition taught by *Hong et al.*

18. Lastly, Applicants argue that the gelling agent of *Hong et al* is an essential ingredient that one of ordinary skill in the art would not have replaced with the gelling agent of *Loffler* (Applicant Argument Pages 14 and 16). Yet, Applicants have not provided any reasoning to support their assertion that the gelling agent disclosed by *Hong et al* is, indeed, so critical to *Hong et al's* composition that one would not consider replacing it with a gelling agent that is taught in the prior art to have numerous advantages. As such, Applicants' argument is not found persuasive.

19. Claims 7-11, 14-24, 26-29 and 38 were also rejected as *prima facie* obvious in the Action mailed on 3/04/2009. Applicants do not traverse the rejection of these claims beyond those arguments already discussed above and not found persuasive. As such, the rejection of claims 7-11, 14-24, 26-29 and 38 is maintained, as reiterated herein:

20. Instant claims 7-11 further define the amount of gelling agent, specifically wherein the composition comprises less than 5% w/w of the gelling agent (claims 7-8), more than 0.5% w/w of the gelling agent (claims 9-10), or 0.1 to 5% w/w of the gelling agent (claim 11). As stated in

> In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)

MPEP 2144.05: . As specifically, stated by *Loffler et al* regarding Aristoflex AVC, "For personal care formulations, the amount required in practice is typically in the range of 0.5-1.0%" (Paragraph 6). Accordingly, the claimed ranges overlap ranges disclosed by the prior art. As such, claims 7-11 are rejected as *prima facie* obvious.

21. Instant claims 14-16 further define the amount of water in the composition. *Hong et al* disclose specific embodiments of hydroalcoholic gels comprising in excess of 38% w/w water (Page 17, Example 8). Accordingly, instant claim 14 is rejected as *prima facie* obvious. As to claims 15 and 16, MPEP 2144.05 states that:

> Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

. In the instant case, the concentration of water in the hydroalcoholic gel composition is clearly a result-effective variable. Alterations in the amount of water would affect the viscosity of the hydroalcoholic gel and thus impact the skin feel of the composition. Accordingly, it would have been customary for an artisan of ordinary skill in the art to determine the optimal amount of water to include in the

formulation in order to best achieve the desired results. See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." Accordingly, claims 15-16 are also rejected as *prima facie* obvious.

22. Claims 17-19 define the cosolvent of the hydroalcoholic gel as ethanol. As discussed above, *Hong et al* teach a hydroalcoholic gel comprising "40~60% by weight of lower alkanol having from one to four carbon atoms" (Abstract). More specifically, *Hong et al* disclose specific embodiments comprising ethanol (Pages 11-14, Examples 1-6 and Pages 17-8, Examples 8-18). Accordingly, claims 17-19 are rejected as *prima facie* obvious.

23. Claims 20-24 further define the amount of cosolvent in the composition, most specifically wherein the composition comprises in excess of 30% (claims 20-23) or not more than 50% (claim 24). *Hong et al* disclose specific embodiments comprising ethanol in the amount of 50% w/w (Page 17, Example 9). As such, claims 20-24 are rejected as *prima facie* obvious.

24. Claims 26-29 further define the amount of salicylic acid in the composition, most specifically wherein the composition comprises at least 0.5% w/w (claims 26-27) or less than 3% w/w (claims 28-29). As discussed above, *Singh et al* teach that "[s]alicylic acid has been approved by the U.S. Food and Drug Administration for the treatment of acne in concentrations of 0.5% to 2% by weight" (Column 1, Lines 16-17). Accordingly, claims 26-29 are *prima facie* obvious.

25. Instant claim 38 is drawn to the composition wherein the composition is in the form of a transparent gel. As stated by Hong et al, "conventional water-soluble polymers such as carboxmethylcellulose… are not proper materials to be used in hydroalcoholic gel compositions according to the present invention because they lose their viscosity or become cloudy" (Page 5, Lines 14-17). Accordingly, it is asserted that the hydroalcoholic gel composition obviated as discussed above would necessarily comprise a transparent gel.

26. New claims 53-54 are drawn to the cosmetically acceptable composition of claim 1 having certain specified properties. In the instant case, it is asserted that the prima facie obvious composition taught by the prior art as discussed above would necessarily comprise the properties recited by instant claims 53-54, absent evidence to the contrary. As stated in *In re Best, Bolton, and Shaw*, "Where… the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product" 195 USPQ 430, 433, 562 F2d 1252 (CCPA 1977). See also *In re Fitzgerald* 205 USPQ 594, 597, 619 F2d 67 (CCPA 1980): the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on." Accordingly, absent evidence to the contrary, new claims 53-54 are rejected as *prima facie* obvious.

27. **Claims 30-37 remain rejected and new claims 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Singh et al* (cited in a previous Action), *Singh and Roberts* (cited in a previous Action), *Hong et al* (cited in a previous Action), *Obata et al***

(cited in a previous Action), and *Loffler et al* (cited in a previous Action) as applied to claims 1 and 25 above, in further view of *Murad et al* (cited in a previous Action).

28. Claims 30-37 were rejected as *prima facie* obvious in the Action mailed on 3/04/2009. Applicants do not traverse the rejection of these claims beyond those arguments already discussed above and not found persuasive. As such, the rejection of claims 30-37 is maintained, as reiterated herein:

29. Claims 30-34 are drawn to the composition which comprises one or more topically active ingredients useful in skin care, including hydrogen peroxide, which reads on claims 30-34. *Murad et al* teach compositions for the treatment and management of skin conditions such as acne comprising hydrogen peroxide (Abstract). As stated in MPEP 2144.06, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose… [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626, F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, it would have been *prima facie* obvious to include hydrogen peroxide in the composition.

30. Claims 35-37 further define the amount of hydrogen peroxide in the composition, most specifically wherein the composition comprises at least 1% w/w (claim 35) or less than 2% w/w (claims 36-37). *Murad et al* generically teach that "[a]dvantageously... the hydrogen peroxide is present in an amount from 0.01 to 6 weight percent" (Paragraph 0024), and specifically disclose an embodiment wherein hydrogen peroxide is present in 1.5% by weight (Paragraph 0068, Example 2). Accordingly, claims 35-37 are rejected as *prima facie* obvious.

31. New claims 49-52 are drawn to the composition of claim 31 wherein tetracyclines (instant claim 49), sulfa drug (instant claim 50), cephalosporin (instant claim 51) and quinolones (instant claim 52) are each further defined. As such, the instant claims 49-52 further limit claim 31. However, claims 49-52 do not require the limitation. As such, the prior art also reads on claims 49-52 which is rejected for the above reasons.

Conclusion

The new ground(s) of rejection presented in this Office action are necessitated by Applicants' amendments to the claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1628

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642